EXHIBIT 58

From: Jay Issa
To: Daniel Sessler
CC: Mark Morken; Michelle Stevens; Jill Rector; Kurz Andrea
Sent: 3/5/2016 4:41:29 PM
Subject: Re: [EXTERNAL] Re: Retro SSI study

> **From:** Jay Issa
> **Sent:** Saturday, March 05, 2016 11:41:28 AM
> **To:** Daniel Sessler
> **CC:** Mark Morken; Michelle Stevens; Jill Rector; Kurz Andrea
> **Subject:** Re: [EXTERNAL] Re: Retro SSI study

Dan,

Thanks a lot for the detailed explanation.
One last point from my point would be the potential noise in the market (one in particular) stating that infection was high when FAW was used. Any thoughts on that one?

Thanks a lot,
-Jay

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On Mar 5, 2016, at 9:17 AM, Daniel Sessler <ds@or.org> wrote:

Hi Mark,

I appreciate this opportunity to provide additional detail and will try to answer your questions.

1) The type of blower and blanket are not recorded in our registry. But if a single type of blower was used during specific periods, we could match cases to blowers by date. That would permit the sort of sub-analysis you propose.

2) Colorectal patients were included in the Sun analysis. However, infection was not an outcome in that paper. The proposed analysis differs in including infectious outcomes and using the appropriate statistical methods for that outcome which differ considerably from those we used previously.

3) Presumably, the infection rates differ because the institutions and definitions differ. Importantly, about half the Clinic cases are inflammatory bowel disease, a group with a high infection rate, where most patients in the 1996 trial had colon cancer. The treatment reported in 1996 is implausibly high (that is, the infection rate probably wasn't actually as low as in our 100 warmed patients). Knowing what we do now about fragile clinical trials, we would never have published such a small study.

4) All patients in the proposed analysis will have been warmed with forced air. But their temperatures will still vary depending on the size and duration of the operation, along with cover selection and ambient temperature. Core temperature over the course of an operation can be characterized with various "curve descriptors" such as mean, low, high, end, area-under-curve, etc. Which is best related to infection remains unknown. Time-weighted average seems like a reasonable primary outcome, but we're open to alternatives since there really isn't any evidence to suggest one versus another. Other curve descriptors will be included in secondary analyses.

Regards, Dan.

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On Mar 4, 2016, at 3:00 PM, Mark Morken <mamorken@mmm.com> wrote:

Hello Dan,

Our group met yesterday to discuss the proposed retrospective review of SSI in Colorectal surgery protocol and we have the following questions or clarifications:

1. Is it possible to determine whether the 505 or 775 units were used and do a sub-analysis in these groups?
2. How is this review different from the Sun review? It looks like 5.5% of the subjects reviewed in Sun were those undergoing colorectal resection with another 5% or so undergoing therapeutic GI procedures (whatever that means).
3. The infection rate in the 1996 study went from 19% to 6.6% and in the background for this protocol the infection rate is 13%-why is there such a difference from what was achieved in 1996 and current status?
4. If there is correlation between time weighted average for hypothermia and SSI and BH is the reference active warmer how will this be interpreted? In addition, the plan is to use weighted average temperature instead of area under the curve as was done for the Sun, et al publication can you provide the rationale?

Thanks,
Mark

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